

# Exhibit 2

US9095563B2	CBD Pain Relief Cream 300mg ("Accused Product")
11. A topical formulation consisting essentially of:	<p>The accused product is a topical formulation (e.g., CBD Cream 300mg).</p> <p>As shown below, the accused product is CBD Pain Relief Cream intended for topical application.</p> <div data-bbox="1021 379 1520 1031" data-label="Image"></div> <p><a href="https://thewelltheory.com/product/cbd-cream/">https://thewelltheory.com/product/cbd-cream/</a></p>
an extract of <i>Cannabis sativa</i> or <i>Cannabis indica</i> ;	<p>The accused product consists of an extract of a Cannabis sativa or Cannabis indica (e.g., Hemp plant).</p> <p>As shown below, the accused product is pain-relief cream formulation which contain 300mg of CBD derived from the hemp plant. The Hemp is the common name for the Cannabis sativa.</p>

### **MEDICAL GRADE INGREDIENTS**

- Full Spectrum CBD
- Lidocaine
- Menthol
- Aloe Vera
- Frankincense + Bergamot + Other Essential Oils
- [Certificate of Analysis](#)

<https://thewelltheory.com/product/cbd-cream/>

## Comprehensive Analysis Report

### Sample Overview

**Client:** Well Theory

None

**Sample Name:** Recovery Cream: 300mg

**Sample Matrix:** Topical Applicant

**Sample Lot:** WTPC24

**Date Received:** 08/20/2024

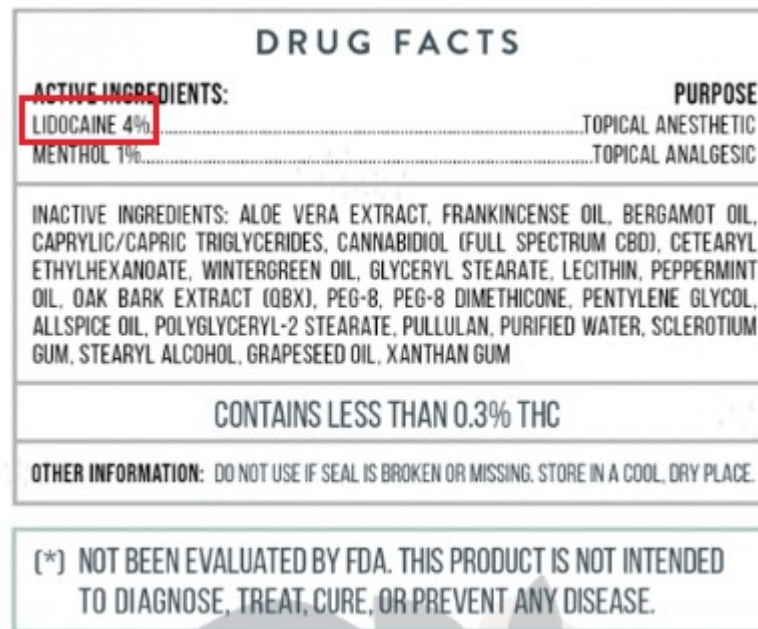
**APRC #:** SAW240821A

Assay	Disposition	Date Tested
Hemp or R&D Cannabinoid Testing (Potency)	Tested	08-21-2024

[https://store-c1dn0kebrh.mybigcommerce.com/content/COA\\_Pain%20Cream.pdf](https://store-c1dn0kebrh.mybigcommerce.com/content/COA_Pain%20Cream.pdf)

	<div>USDA Introduces a Multi-Year Plan to Strengthen U.S. Genebank Management of Plant Germplasm</div> <div><div>Taxon: <u>Cannabis sativa L.</u></div><div>New Species Search</div></div> <div><div>Nomenclature</div><div>Common Names</div><div>Distribution</div><div>Economic Uses</div></div> <div><div>Common names</div><div><div>Excel</div><div>Search: <input type="text"/></div></div><div>Showing 1 to 9 of 9 entries</div><div>Show <div>10</div> entries</div><div>Search: <input type="text"/></div></div> <table><thead><tr><th>Language</th><th>Name</th><th>Alternate name</th><th>note</th><th>Citation</th></tr></thead><tbody><tr><td>Chinese</td><td>da ma</td><td>大麻</td><td></td><td>Wu Zheng-yi &amp; P. H. Raven et al., eds. 1994-. <a href="#">Flora of China (English edition)</a>.</td></tr><tr><td>English</td><td>hemp</td><td></td><td></td><td>Botanical Society of the British Isles. <a href="#">BSBI taxon database (on-line resource)</a>.</td></tr></tbody></table> <div><a href="https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomydetail?id=8862">https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomydetail?id=8862</a></div>	Language	Name	Alternate name	note	Citation	Chinese	da ma	大麻		Wu Zheng-yi & P. H. Raven et al., eds. 1994-. <a href="#">Flora of China (English edition)</a> .	English	hemp			Botanical Society of the British Isles. <a href="#">BSBI taxon database (on-line resource)</a> .
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at least one component selected from the group consisting of capsaicin, benzocaine, lidocaine, camphor,	<p>The accused product contains at least one compound selected from the group consisting of capsaicin, benzocaine, lidocaine, camphor, benzoin resin, methylsalicylate, triethanolamine salicylate, hydrocortisone, and salicylic acid, present in an amount of at least 0.1 wt % in the topical formulation.</p> <p>As shown below accused product contain 4% lidocaine as an active ingredient which is more than 0.1 wt % in the topical formulation.</p>															

benzoin resin, methylsalicylate, triethanolamine salicylate, hydrocortisone, and salicylic acid, present in an amount of at least 0.1 wt % in the topical formulation,



<https://thewelltheory.com/product/cbd-cream/>

wherein the concentration of cannabidiol in the topical formulation is greater than 2 milligrams per kilogram in the topical formulation,

The accused product has concentration of cannabidiol in the topical formulation is greater than 2 milligrams per kilogram in the topical formulation.

As shown below accused product contain 300mg of cannabidiol (CBD) which is greater than 2 milligrams per kilogram. (Total volume of formulation is 1FL OZ)



<https://thewelltheory.com/product/cbd-cream/>

Method: SOP 1-2026.03

Sample Name: Recovery Cream: 300mg

APRC Lot Number: SAW240821A

Cannabinoid	RT	Total %	Total mg/g
Cannabidivarinic Acid (CBDVA)	ND	ND	ND
Cannabidivarin (CBDV)	ND	ND	ND
Cannabidiolic Acid (CBDA)	ND	ND	ND
Cannabigerolic Acid (CBGA)	ND	ND	ND
Cannabinol (CBN)	ND	ND	ND
Cannabidiol (CBD)	3.33	1.05	10.53
Cannabigerol (CBG)	ND	ND	ND
Tetrahydrocannabivarin (THCV)	ND	ND	ND
Tetrahydrocannabivarin Acid (THCVA)	ND	ND	ND
Delta-9-Tetrahydrocannabinol ( $\Delta$ 9-THC)	ND	ND	ND
Delta-8-Tetrahydrocannabinol ( $\Delta$ 8-THC)	ND	ND	ND
Tetrahydrocannabinolic acid (THCA-A)	ND	ND	ND
Cannabichromene (CBC)	ND	ND	ND
Cannabichromene Acid (CBCA)	ND	ND	ND
$\Delta$ 10 and $\Delta$ 6a,10a-Tetrahydrocannabinol, mixed isomers	ND	ND	ND
(6aR,9R)- $\Delta$ 10-Tetrahydrocannabidiol	NT	NT	NT
(6aR,9S)- $\Delta$ 10-Tetrahydrocannabidiol	NT	NT	NT
9(R+S)- $\Delta$ 6a,10a-Tetrahydrocannabidiol	NT	NT	NT
Cannabicitran (CBTC)	ND	ND	ND

[https://store-c1dn0kebrh.mybigcommerce.com/content/COA\\_Pain%20Cream.pdf](https://store-c1dn0kebrh.mybigcommerce.com/content/COA_Pain%20Cream.pdf)

said topical formulation obtained by dispersing the

The accused product is a topical formulation obtained by dispersing the extract of *Cannabis sativa* or *Cannabis indica* in a water-in-oil emulsion, an oil-in-water emulsion, a wax-in-oil base, or an oil-in-wax base.



extract of *cannabis sativa* or *cannabis indica* in a water-in-oil emulsion, an oil-in-water emulsion, a wax-in-oil base, or an oil-in-wax base

The accused product is a topical cream formulation which contains extract from the broad-spectrum Hemp plant dispersed in a cream base.

The cream is an emulsion semisolid dosage form that contains >20% water and/or <50% of hydrocarbons, waxes, or polyethylene glycols as the vehicle for external application to the skin. Hence accused product is obtained by dispersing the extract of broad-spectrum Hemp plant in oil-in-water or water-in-oil emulsion.

Table 3  
Suggested definitions of topical dosage forms

Dosage form <sup>a</sup>	Definition	Formulation	Appearance and feel	Physical properties
Topical solution	A clear, homogeneous liquid <sup>b</sup> dosage form for external application to the skin	Usually contains an aqueous or alcoholic vehicle; though an oil may also serve as the vehicle. May contain a gelling agent to thicken the solution	Clear, thin	
Topical suspension	A liquid <sup>b</sup> dosage form, that consists of a solid suspended in a liquid vehicle in a two-phase system for external application to the skin	Usually contains an aqueous or alcoholic vehicle	Solid often settles with time, thus requiring shaking before use	
Lotion	An emulsion <sup>c</sup> liquid <sup>b</sup> dosage form for external application to the skin	Usually contains an aqueous vehicle and >50% water and volatiles <sup>d</sup>	Opaque, thin, non-greasy; tends to evaporate rapidly with a cooling sensation when rubbed onto the skin	Exhibits Newtonian or pseudoplastic flow behavior
Gel	A semisolid <sup>e</sup> dosage form that contains a gelling agent to provide stiffness to a solution or colloidal dispersion <sup>f</sup> for external application to the skin. A gel may contain suspended particles	Usually contains an aqueous or alcoholic vehicle and a gelling agent such as starch, cellulose derivatives, carbomers, magnesium–aluminum silicates, xanthan gum, colloidal silica, aluminum or zinc soaps <sup>g</sup>	Usually clear or translucent in a single-phase system; otherwise opaque in a two-phase system; thick, non-greasy; provides a cooling sensation when applied to the skin	Usually exhibits a single transition in TGA <sup>h</sup> corresponding to loss of the vehicle; does not flow at low shear stress and generally displays plastic flow behavior
Cream	An emulsion <sup>c</sup> semisolid <sup>e</sup> dosage form that contains >20% water and volatiles <sup>d</sup> and/or <50% of hydrocarbons, waxes, or polyethylene glycols as the vehicle for external application to the skin	Contains >20% water and volatiles <sup>d</sup> and/or <50% of hydrocarbons, waxes, or polyethylene glycols as the vehicle. There are two types of creams: an oil-in-water cream with water as the continuous phase and a water-in-oil cream with oil as the continuous phase	Opaque, viscous, non-greasy to mildly greasy; tends to mostly evaporate or be absorbed when rubbed onto the skin	Exhibits two or more transitions in TGA <sup>h</sup> indicative of at least a two-phase system; displays plastic flow behavior
Ointment	A suspension or emulsion semisolid <sup>e</sup> dosage form that contains <20% water and volatiles <sup>d</sup> and >50% of hydrocarbons, waxes, or polyethylene glycols as the vehicle for external application to the skin	Contains <20% water and volatiles <sup>d</sup> and >50% of hydrocarbons, waxes, or polyethylene glycols as the vehicle	Opaque or translucent, viscous, greasy; tends not to evaporate or be absorbed when rubbed onto the skin	
Paste	A semisolid <sup>e</sup> dosage form that contains a large proportion (i.e., 20–50%) of solids finely dispersed in a fatty vehicle for external application to the skin	Contains a large proportion (20–50%) of dispersed solids in a fatty vehicle	Opaque, viscous, greasy to mildly greasy; adheres well to the skin, forming a protective layer	

<https://www.sciencedirect.com/science/article/abs/pii/S037851730500102X?via%3Dihub>

consisting essentially of at least one component selected from the group consisting of capsaicin, benzocaine, lidocaine, camphor, benzoin resin, methylsalicylate, triethanolamine salicylate, hydrocortisone, and salicylic acid.

The accused product contains at least one compound selected from the group consisting of capsaicin, benzocaine, lidocaine, camphor, benzoin resin, methylsalicylate, triethanolamine salicylate, hydrocortisone, and salicylic acid.

As shown below accused product contain lidocaine as active ingredient present in the formulation.

DRUG FACTS	
ACTIVE INGREDIENTS:	PURPOSE
LIDOCAINE 4%	TOPICAL ANESTHETIC
MENTHOL 1%	TOPICAL ANALGESIC
INACTIVE INGREDIENTS: ALOE VERA EXTRACT, FRANKINCENSE OIL, BERGAMOT OIL, CAPRYLIC/CAPRIC TRIGLYCERIDES, CANNABIDIOL (FULL SPECTRUM CBD), CETEARYL ETHYLHEXANOATE, WINTERGREEN OIL, GLYCERYL STEARATE, LECITHIN, PEPPERMINT OIL, OAK BARK EXTRACT (QBX), PEG-8, PEG-8 DIMETHICONE, PENTYLENE GLYCOL, ALLSPICE OIL, POLYGLYCERYL-2 STEARATE, PULLULAN, PURIFIED WATER, SCLEROTIUM GUM, STEARYL ALCOHOL, GRAPESEED OIL, XANTHAN GUM	
CONTAINS LESS THAN 0.3% THC	
OTHER INFORMATION: DO NOT USE IF SEAL IS BROKEN OR MISSING. STORE IN A COOL, DRY PLACE.	
(*) NOT BEEN EVALUATED BY FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.	

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